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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/053,510

Applicant(s)

SABA ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of the Application***

Claims 1-30 are pending.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, drawn to a recombinant vector, host cells and a method of preparing a sphingosine-1-phosphate lyase encoded by the polynucleotide of SEQ ID NO: 15, classified in class 536, subclass 23.2.
  - II. Claims 4-6, drawn to a method for identifying an agent that modulates sphingosine-1-phosphate lyase activity, classified in class 435, subclass 232.
  - III. Claims 7-8, drawn to a composition comprising an agent that modulates sphingosine-1-phosphate lyase activity, wherein the agent is a polynucleotide, classified in class 536, subclass 23.1.
  - IV. Claims 7, 9, 23, 25, drawn to an antibody against the polypeptide of SEQ ID NO: 16, classified in class 530, subclass 387.1.
  - V. Claims 10-22, drawn to a method for inhibiting growth of a cancer cell or a method for inhibiting the development of metastasis in a mammal by increasing sphingosine-1-phosphate lyase activity, classified in class 514, subclass 1.
  - VI. Claim 24, drawn to a method for detecting a sphingosine-1-phosphate lyase, classified in class 436, subclass 501.
  - VII. Claim 26, drawn to a null mutant *Drosophila melanogaster* fly, classified in class 800, subclass 8.

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VIII. Claims 27-29, drawn to a method for identifying an agent that modulates sphingosine-1-phosphate lyase activity, classified in class 800, subclass 3.

IX. Claim 30, drawn to a method for detecting cancer in a patient, classified in class 436, subclass 94.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, III, IV, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I, III, IV, and VII each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA in Inventions I and III comprise a nucleic acid sequence, the null mutant fly of Invention VII is a multicellular organism whereas the antibody of Invention IV is a protein. In addition, the DNA in Inventions I and III are unrelated. Neither the DNA of Inventions I or III nor the fly of Invention VII are required for the production of the antibody of Invention IV. Also, the DNA of Invention I has other uses besides creating a null mutant fly, such as the recombinant production of the corresponding protein, as a hybridization probe or in gene therapy. In addition, the DNA of Invention III is not used in creating a null mutant fly.

3. Inventions II, V, VI, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

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instant case the methods of inventions II, V, VI, VIII and IX comprise different steps, may use different products, have different effects and produce different results.

4. Inventions I, II, VI, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA of Invention I is neither made nor used by the methods of Inventions II, VI, VIII or IX.

5. Inventions III, II, V, VI, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the composition of Invention III is neither made nor used by the methods of Inventions II, VI, VIII or IX. The composition of Invention III is not made by the method of Invention V. Also, the composition of Invention III can comprise an agent which inhibits sphingosine-1-phosphate lyase activity, therefore cannot be used in the method of Invention V.

6. Inventions IV, II, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Invention IV is neither made nor used by the methods of Inventions II, VIII or IX.

7. Inventions VII, II, V, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the fly of Invention VII is neither made nor used by the methods of Inventions II, V, or IX.

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8. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention I can be used to recombinantly produce the corresponding protein as well as in the method of Invention V.

9. Inventions IV and V or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention IV can be used in protein purification as well as in the patentably distinct methods of Inventions V or VI.

10. Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of invention VIII can be practiced with the protein of SEQ ID NO: 16 as well as with the fly of Invention VII.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

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12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

15. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
February 21, 2003

  
PONNATHAPURA ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
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